VERMONT

AGENCY OF HUMAN SERVICES

DEPARTMENT OF DISABILITIES, AGING AND INDEPENDENT LIVING

Division of Licensing and Protection
103 South Main Street
Waterbury VT 05671-2306
http://www.dail.vermont.gov
Voice/TTY (802) 871-3317
To Report Adult Abuse: (800) 564-1612
Fax (802) 871-3318

April 27, 2015

Dr. John Brumsted, Administrator
University Of Vermont Medical Center
111 Colchester Ave
Burlington, VT 05401

Provider ID #: 470003

Dear Dr. Brumsted:

The Division of Licensing and Protection completed a survey at your facility on March 19, 2015. The purpose of the survey was to determine if your facility met the conditions of participation for Acute Care Hospitals found in 42 CFR Part 482.

Following the survey, your facility submitted a Plan of Corrections (POC) which was found to be acceptable on April 8, 2015.

Sincerely,

Suzanne E. Leavitt RN, MS

Suzanne Leavitt, RN, MS
Assistant Division Director
Director State Survey Agency

Enclosure

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V 000 INITIAL COMMENTS

An unannounced on-site complaint investigation was conducted by the Division of Licensing and Protection from 3/16/15 through 3/19/15 to determine compliance with Condition of Participation for: Patient Rights; Nursing Services, Quality Assurances/Performances Improvement, Medical Staff, Governing Body, Pharmaceutical Services and Anesthesia Services for Complaint# 00013152. The following regulatory violations were identified:

Based on information gathered, the hospital was determined not to be in compliance with Conditions of Participation for: Patient Rights and Quality Assessment Performance Improvement, Pharmaceutical Services and Nursing Services. Based on information gathered at the time of survey, an Immediate Jeopardy situation was determined to exist based on the hospital's failure to initiate immediate action after a significant medication error was committed.

The Conditions of Participation for Nursing Services, Patient Rights, Quality Assessment/Performance Improvement and Pharmaceutical Services were not met.

Note: The Immediate Jeopardy was removed by the hospital on 3/18/15 at 5:05 PM when a plan to correct the Immediate Jeopardy was accepted.

PLAN OF CORRECTION

A 115 482.13 PATIENT RIGHTS

A hospital must protect and promote each patient's rights.

This CONDITION is not met as evidenced by:

Based on staff interview and record review the Condition of Participation: Patient Rights was not met as evidenced by the hospital's failure to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient.

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Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

- An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

  As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

PoC accept 4.8.15
F McGrath / SDA

PLAN OF CORRECTION

A 144 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING

The patient has the right to receive care in a safe setting.

This STANDARD is not met as evidenced by: Based on staff interview and record review the hospital failed to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient. (Patient #1) Findings include:

Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BiPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it was determined the patient required

admission.

Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory, Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI (a standard of care in emergency airway management for intubations not anticipated to be difficult when medications are administered simultaneously to render a patient unconscious to facilitate endotracheal intubation).

For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg). Both medications were ordered to be administered IV (Intravenously) Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 document: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped."

Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought I only hao 1DO mg. in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care.

The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 11:22 AM, MICU Nurse #2 stated when a physician gives a verbal order

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for a medication during an intubation or cardiac arrest s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipation that they physician might order sequential doses.

Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is"... you draw up what the order is and that is what is expected ..." of nurses.

In addition, although a Root Cause Analysis (RCA) was developed on 1/29/15 and 3 action plans were formulated to improve patient safety and nursing practice, as of 3/17/15 none of the plans had been initiated. It was not until an Immediate Jeopardy was determined to exist on 3/18/15 the hospital took immediate corrective action to ensure patient safety by replacing Ketamine 500 mg multidose vials with 200 mg. vials in all RCI medication kits; Nursing Services received direction regarding drawing up only the dose ordered by providers and a review of "read back" process was reinforced.
Refer to Tags: A-0286; 0405 & 500

Action Plan

- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result of this review, the improvement plans were approved for implementation.

- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as of 4/3/2015.

- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.

- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the

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University of Vermont Medical Center Sentinel/Serious Adverse Event Process Flow to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/2015. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.

- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication. The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.

- An educational curriculum that supports practices outlined in the revised MODAR policy was developed by the Directors of Nursing. The Vice President of Nursing communicated the expectation that all scheduled staff is required to complete the curriculum which includes a tutorial and scenario based competency assessment by 4/16/2015. In addition to this education, related content will be added to new nursing orientation effective 4/16/2015.

- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).

- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.

- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.

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- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.

- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product, a change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.

- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the policy revisions effective 4/3/2015.

- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.

- Kit contents will be managed and monitored through the "KitCheck" system. This system allows for medication tracking of lot number and kit accuracy through the use of radiofrequency identification tags.

POC accepted 4/8/15
F. McGrath/SL

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PLAN OF CORRECTION

A 263 482.21 QAPI

The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

This CONDITION is not met as evidenced by: The Condition of Participation: Quality Assurance and Performance Improvement (QNPI) was not met as evidenced by the failure of the hospital to implement an effective hospital-wide action plan after a significant adverse patient event had occurred.

Refer to Tag -A- 0286, 0405 & 500

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

- An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

  As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

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PLAN OF CORRECTION

A 286 482.21 (a), (c)(2), (e)(3) PATIENT SAFETY

(a) Standard: Program Scope
(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors.
(2) The hospital must measure, analyze, and track ...adverse patient events ...

(c) Program Activities .....
(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: ...
(3) That clear expectations for safety are established.

This STANDARD is not met as evidenced by: Based on staff interview and record review there was a failure of Quality Assurance/Performance Improvement to effectively evaluate, fully analyze and fully implement immediate actions when a significant adverse patient event occurred. (Patient #1) Findings include:

On 1/27/15 Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and in respiratory distress.
Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation
as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory
Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI to secure an airway for Patient #1.

For the emergent intubation the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20

minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 1OD mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 1 DO mg. amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx. 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse. Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of Ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome .....I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped." Shortly after the incident a "Safe Report" was filed (Adverse Event Report) and on 1/29/15 a Root Cause Analysis (RCA) was conducted which included staff involved in the event on 1/27/15 along with the Director tor Critical Care, Medication Safety Coordinator, Director of Critical Care Nursing and a ONPI consultant.

Per interview on 3/16/15 at "12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the Resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial throughout the hospital. This would provide a safety barrier in preventing to larger of a dose of Ketamine being drawn and administered during a RCI noting Nurse #"1 had drawn and administered a dose greater then what was prescribed. The Director confirmed, although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the RGI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require.

A second action plan was to developed policy practice guidelines for administering medications noting that Nurse # 1 had drawn up a larger dose of Ketamine, deviating from the physician order. Per interview with Nurse #1 on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time

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of the RSI s/he had anticipated Patient #1 would require more Ketamine due to the patient's weight so s/he decided to draw up more then what the physician had ordered. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication then ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care. Deviating from the physician's order during an emergent procedure was confirmed by the Nurse Manager of MICU on 1/17/15 at 9:45 AM as still presently going on with some nurses practicing in MICU.

A third action plan was reinforcing the "closed loop communication" process between physicians and the nurse during emergent procedures. The Director of Patient Safety and Quality confirmed Nurse #1 did repeat back to the physician what the verbal order was (Ketamine 100 mg) and acknowledged 100 mg. of Ketamine was being administered, however Nurse #1 pushed intravenously 500 mg.

When determining what had been enacted upon of the 3 areas identified from the RCA, it was confirmed multidose vials of Ketamine 100 mg/Sec still remained in all of the RCI medication boxes throughout the hospital. Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services.

A hospital wide education of nurses reinforcing standards of nursing practice regarding following physician orders and not drawing up more medication then what was ordered had not been addressed. Although the MICU Nursing Council meeting on 2/20/15 discussed the event of 1/27/15 there was a failure to implement a hospital wide directive to nurses regarding drawing up only what the physician has ordered. In addition, it was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 the nursing practice of drawing up more medication then what was ordered during an emergent procedure was probably still being performed by some nurses in MICU.

In regards to the "close loop communication", the Medical Director of Adult Critical Care Services confirmed on 3/18/15 at 10:15 AM although s/he has brought the incident to the attention of physicians practicing in MICU, reminding them to continue close communication practice with nurses involved during emergent procedures, s/he failed to share the incident and concerns with Surgical Intensive Care Unit (ICU) or to other directors who provide supervision where Ketamine may be used during RCI.

It was not until an Immediate Jeopardy situation was determined to exist, when the hospital made the necessary changes to assure care was provided in a safe setting. The multidose vials of 500 mg of

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Ketamine were exchanged for 200 mg vials in all RCI medication boxes. Under the Direction of the VP of Nursing Services the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and deployed throughout all nursing services. In addition, the module reinforced the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider.

Action Plan

- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result of this review, the improvement plans were approved for implementation.

- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as of 4/3/2015.

- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.

- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the University of Vermont Medical Center Sentinel/Serious Adverse Event Process Flow to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/15. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.

- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication.

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The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.

- An educational curriculum that supports practices outlined in the revised MODAR policy was developed by the Directors of Nursing. The Vice President of Nursing communicated the expectation that all scheduled staff is required to complete the curriculum which includes a tutorial and scenario based competency assessment by 4/16/2015. In addition to this education, related content will be added to new nursing orientation effective 4/16/2015.

- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).

- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.

- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.

- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.

- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product, a change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy

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technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.

- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the policy revisions on 4/3/2015.
- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.
- Kit contents will be managed and monitored through the "KitCheck" system. This system allows for medication tracking of lot number and kit accuracy through the use of radiofrequency identification tags.

POC agent 4.8.15
Simonton 15

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PLAN OF CORRECTION

A385 482.23 NURSING SERVICES

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

This CONDITION is not met as evidenced by: Based on staff interview and record review, the Condition of Participation: Nursing Services was not met based on hospital nursing staff's failure to follow physician orders for the administration of an intravenous medication and administering a dose greater then what was ordered.

Refer to TAG: A- 0405

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

- An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

  As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

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PLAN OF CORRECTION

A405 482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION OF DRUGS

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482..12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

This STANDARD is not met as evidenced by: Based on staff interview and record review, a Registered Nurse (RN) failed to prepare and administer a medication in accordance with the orders of the practitioner responsible for the patient's care and in accordance with hospital policy and standards of nursing practice for 1 of 10 applicable patients. (Patient #1) Findings include:

Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BiPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibtotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it was determined the patient required admission.

Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI.

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For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome. Could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped."

Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care.

The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 1:22 AM, MICU Nurse #2 stated when a physician gives a verbal order for a medication. During an intubation or cardiac arrest, s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the

syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipatton that the Physician might order sequential doses. However, per interview on 3/18/15 at 10:15 AM the Medical Dtrector of Adult Critical Care Services acknowledged the drawing up of more medication by nurses then what the physician has ordered during an emergency procedure creates "...a potential for error".

Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is"--- you draw up what the order is and that is what is expected ..." of nurses.Per hospital policy Intravenous Medications; Preparation and Administration of: by RNs and LPNs published on 7/29/14 states" 3. A RN will administer medications via IV push as ordered by a physician and dispensed by the pharmacy."

Action Plan

- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication. The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.

- An educational curriculum that supports practices outlined in the revised MODAR policy was developed by the Directors of Nursing. The Vice President of Nursing communicated the expectation that all scheduled staff is required to complete the curriculum which includes a tutorial and scenario based competency assessment by 4/16/2015. In addition to this education, related content will be added to new nursing orientation effective 4/16/2015.

- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).

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- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.

- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.

POC account 4.9.15
F. McIntosh RN

PLAN OF CORRECTION

A 490 482.25 PHARMACEUTICAL SERVICES

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

This CONDITION is not met as evidenced by: The Condition of Participation: Pharmacy Services was not met due to the failure of Pharmacy Services to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital.

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

- An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

  As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only

the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

PLAN OF CORRECTION

A 500 482.25(b) DELIVERY OF DRUGS

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

This STANDARD is not met as evidenced by: Based on observations, interview and record review the Pharmacy Services failed to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital. (Patient #1) Findings include:

During an emergent intubation of a patient in MICU on 1/27/15 the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 1OD mg. amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650- 1655 (4:50- 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

Per interview on 3/16/15 at 12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial throughout the hospital. This would provide a safety barrier in preventing a larger dose of Ketamine being drawn and administered during a RGI, noting Nurse #1 had drawn and administered a dose greater then what was prescribed. The Director confirmed although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the

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RGI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require. Per observation in MICU on 3/17/15 at 8:40 AM, the RGI medication boxes still contained Ketamine 100 mg/5 cc multidose vials.

Per interview on 3/16/15 at 4:10 PM a pharmacist who is the medication safety coordinator confirmed s/he was involved with the RCA and was working on an action plan to replace the multidose vials of 500 mg of Ketamine. "We are pretty close to the result of having a 10 mg/ml vial and 20 cc vial (200 mg)" and further noting the ICUs never use more than 200 mg of Ketamine during an event. The pharmacist also acknowledged a shortage of Ketamine and that further discussions with Anesthesia Services was needed prior to making any changes in Ketamine concentration. The pharmacist further acknowledged proper medication administration is looking at the vial and making sure you have the right dose.

Per interview on 3/17/15 at 1:00 PM, the Chief of Anesthesiology acknowledged Anesthesia Services has 2 concentrations of Ketamine, 10 mg/1 cc and 100 mg/1 cc available for the provision of patient care. The Chief of Anesthesiology stated several years ago his/her service requested pharmacy to provide pre-drawn syringes of Ketamine, very low doses of Ketamine 0.1 and 0.2 mg/kg used as an adjunct to reduce opioid dosing. Anesthesia Services does have access to Ketamine 100 mg/1 cc in Pyxis (automated medication station) but there are alerts to assure the right dose is being used.

Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services. On 3/19/15 12:10 PM, the Pharmacy Manager for Clinical Practice confirmed Ketamine 500 mg mutidose vials had been removed from all the RCI boxes and replaced with 200 mg Ketamine vials.

Action Plan

- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result, the plans were approved for implementation.
- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as 4/3/2015.
- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.
- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient

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Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the University of Vermont Medical Center Sentinel/Serious Adverse Event Process Flow to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/15. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.

- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.

- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product the change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.

- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the respective policy revisions effective 4/3/2015.

- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.

- Kit contents will be managed and monitored through the "KitCheck" system. This system allows for medication tracking of lot number and kit accuracy through the use of radiofrequency identification tags.

POC accept 4-8-15
[illegible]/SGA

THE
University of Vermont
MEDICAL CENTER

April 2, 2015

J. William Roberson
Associate Regional Administrator
Northeast Division, Survey & Certification
Department of Health and Human Services
Centers for Medicaire and Medicaid Services
JKF Federal Building, Government Center
Room 2325
Boston, MA 02203

Re: CMS Certification Number: 470003
Survey ID: 9HZ611, 03/19/2015
Initial Notice of Termination

Dear Mr. Roberson,

I am submitting Form CMS -2567 and the attached Plan of Correction in response to the Statement of Deficiencies from the survey completed by the State of Vermont Division of Licensing and Protection on March 19, 2015.

The University of Vermont Medical Center is committed to continuously improving the quality of care and services we provide to our patients. As part of our ongoing performance improvement efforts I have attached our response to the regulatory deficiencies cited.

If you have any questions regarding the attached Plan of Correction or require further clarification, please do not hesitate to contact me.

Sincerely,

Anna Noonan

Anna Noonan
Vice President, Jeffords Institute for Quality
The University of Vermont Medical Center
111 Colchester Avenue
Burlington, Vermont 05401
Phone: 802-847-4970
Fax: 802-847-6274

PRINTED: 03/24/2015
FORM APPROVED
OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	470009	A. BUILDING _____ B. WING _____	C 03/19/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNIVERSITY OF VERMONT MEDICAL CENTER	111 COLCHESTER AVE BURLINGTON, VT 05401

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS An unannounced on-site complaint investigation was conducted by the Division of Licensing and Protection from 3/10/15 through 3/19/15 to determine compliance with Condition of Participation for: Patient Rights; Nursing Services, Quality Assurances/Performances Improvement, Medical Staff, Governing Body, Pharmaceutical Services and Anesthesia Services for Complaint # 00013152. The following regulatory violations were identified: Based on information gathered, the hospital was determined not to be in compliance with Conditions of Participation for: Patient Rights and Quality Assessment/Performance Improvement, Pharmaceutical Services and Nursing Services. Based on information gathered at the time of survey, an Immediate Jeopardy situation was determined to exist based on the hospital's failure to initiate immediate action after a significant medication error was committed. The Conditions of Participation for Nursing Services, Patient Rights, Quality Assessment/Performance Improvement and Pharmaceutical Services were not met. Note: The Immediate Jeopardy was removed by the hospital on 3/18/15 at 6:05 PM when a plan to correct the Immediate Jeopardy was accepted.	A 000		
A 115	482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on staff interview and record review the	A 115	SEE ATTACHED PLAN of Correction	4/17/15

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 115	Continued From page 1 Condition of Participation: Patient Rights was not met as evidenced by the hospital's failure to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient. Refer to Tag: A - 0144 & 286	A 115		
A 144	482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on staff interview and record review the hospital failed to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient. (Patient #1) Findings include: Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BIPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it	A 144	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 144	Continued From page 2 was determined the patient required admission. Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI (a standard of care in emergency airway management for intubations not anticipated to be difficult when medications are administered simultaneously to render a patient unconscious to facilitate endotracheal intubation). For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg). Both medications were ordered to be administered IV (intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc	A 144	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 144	Continued From page 3 of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 6:16 PM; The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome.....I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped." Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the	A 144	See ATTACHED PLAN of Correction	4/17/15

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A 144	Continued From page 4 physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care. The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 11:22 AM, MICU Nurse #2 stated when a physician gives a verbal order for a medication during an intubation or cardiac arrest, s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipation that they physician might order sequential doses. Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently	A 144	See ATTACHED PLAN of Correction	4/17/15

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A 144	Continued From page 5 had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is "... you draw up what the order is and that is what is expected..." of nurses. In addition, although a Root Cause Analysis (RCA) was developed on 1/29/15 and 3 action plans were formulated to improve patient safety and nursing practice, as of 3/17/15 none of the plans had been initiated. It was not until an Immediate Jeopardy was determined to exist on 3/18/15 the hospital took immediate corrective action to ensure patient safety by replacing Ketamine 500 mg multidose vials with 200 mg. vials in all RCI medication kits; Nursing Services received direction regarding drawing up only the dose ordered by providers and a review of "read back" process was reinforced. Refer to Tags: A-0286; 0405 & 500	A 144	SEE ATTACHED PLAN OF CORRECTION	4/9/15
A 263	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	A 263		

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A 263	Continued From page 6 This CONDITION is not met as evidenced by: The Condition of Participation: Quality Assurance and Performance Improvement (QA/PI) was not met as evidenced by the failure of the hospital to implement an effective hospital-wide action plan after a significant adverse patient event had occurred. Refer to Tag - A- 0286, 0405 & 500	A 263		
A 286	482.21(a), (c)(2), (e)(3) PATIENT SAFETY (a) Standard: Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors. (2) The hospital must measure, analyze, and track ...adverse patient events ... (c) Program Activities ..... (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. (e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: ... (3) That clear expectations for safety are established.	A 286	SEE ATTACHED PLAN of CORRECTION	4/17/15

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A 286	Continued From page 7 This STANDARD is not met as evidenced by: Based on staff interview and record review there was a failure of Quality Assurance/Performance Improvement to effectively evaluate, fully analyze and fully implement immediate actions when a significant adverse patient event occurred. (Patient #1) Findings include: On 1/27/15 Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI to secure an airway for Patient #1. For the emergent intubation the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV	A 286	SEE ATTACHED PLAN of Correction	4/17/15

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A 286	Continued From page 8 (intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM. The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of Ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome.....I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped." Shortly after the incident a "Safe Report" was filed (Adverse Event Report) and on 1/29/15 a Root Cause Analysis (RCA) was	A 286	SEE ATTACHED PLAN OF CORRECTION	

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A 286	Continued From page 9 conducted which included staff involved in the event on 1/27/15 along with the Director for Critical Care, Medication Safety Coordinator, Director of Critical Care Nursing and a QA/PI consultant. Per interview on 3/16/15 at 12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the Resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial throughout the hospital. This would provide a safety barrier in preventing to larger of a dose of Ketamine being drawn and administered during a RCI noting Nurse #1 had drawn and administered a dose greater than what was prescribed. The Director confirmed, although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the RCI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require. A second action plan was to developed policy practice guidelines for administering medications noting that Nurse #1 had drawn up a larger dose of Ketamine, deviating from the physician order. Per interview with Nurse #1 on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had anticipated Patient #1 would require more Ketamine due to the patient's weight so s/he decided to draw up more than	A 286	566 ATTACHED PLAN OF CORRECTION	4/17/15

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A 286	Continued From page 10 what the physician had ordered. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication then ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care. Deviating form the physician's order during an emergent procedure was confirmed by the Nurse Manager of MICU on 1/17/15 at 9:45 AM as still presently going on with some nurses practicing in MICU. A third action plan was reinforcing the "closed loop communication" process between physicians and the nurse during emergent procedures. The Director of Patient Safety and Quality confirmed Nurse #1 did repeat back to the physician what the verbal order was (Ketamine 100 mg) and acknowledged 100 mg. of Ketamine was being administered, however Nurse #1 pushed intravenously 500 mg. When determining what had been enacted upon of the 3 areas identified from the RCA, it was confirmed multidose vials of Ketamine 100 mg/5cc still remained in all of the RCI medication boxes throughout the hospital. Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services.	A 286	SEE ATTACHED PLAN of CORRECTION	4/8/15

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A 286	Continued From page 11 A hospital wide education of nurses reinforcing standards of nursing practice regarding following physician orders and not drawing up more medication then what was ordered had not been addressed. Although the MICU Nursing Council meeting on 2/20/15 discussed the event of 1/27/15 there was a failure to implement a hospital wide directive to nurses regarding drawing up only what the physician has ordered. In addition, it was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 the nursing practice of drawing up more medication then what was ordered during an emergent procedure was probably still being performed by some nurses in MICU. In regards to the "close loop communication", the Medical Director of Adult Critical Care Services confirmed on 3/18/15 at 10:15 AM although s/he has brought the incident to the attention of physicians practicing in MICU, reminding them to continue close communication practice with nurses involved during emergent procedures, s/he failed to share the incident and concerns with Surgical Intensive Care Unit (ICU) or to other directors who provide supervision where Ketamine may be used during RCI. It was not until an Immediate Jeopardy situation was determined to exist, when the hospital made the necessary changes to assure care was provided in a safe setting. The multidose vials of 500 mg of Ketamine were exchanged for 200 mg vials in all RCI medication boxes. Under the Direction of the VP of Nursing Services the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and deployed throughout all nursing	A 286	SEE ATTACHED PLAN of Correction	4/27/15

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A 286	Continued From page 12 services. In addition, the module reinforced the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider.	A 286		
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on staff interview and record review, the Condition of Participation: Nursing Services was not met based on hospital nursing staff's failure to follow physician orders for the administration of an intravenous medication and administering a dose greater than what was ordered.	A 385	SEE ATTACHED PLAN OF CORRECTION	4/17/15
A 405	Refer to TAG: A- 0405 482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION OF DRUGS (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and	A 405	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 405	Continued From page 13 regulations. (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures. This STANDARD is not met as evidenced by: Based on staff interview and record review, a Registered Nurse (RN) failed to prepare and administer a medication in accordance with the orders of the practitioner responsible for the patient's care and in accordance with hospital policy and standards of nursing practice for 1 of 10 applicable patients. (Patient #1) Findings include: Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BIPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it was determined the patient required admission.	A 405	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 405	Continued From page 14 Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI. For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromusoular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:59 PM Patient #1 was	A 405	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 405	Continued From page 15 In cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1656 (4:50 - 4:56 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM. The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome.....I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped." Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the physician would order more to be administerd during the procedure. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done	A 405	SEE ATTACHED PLAN of Correction	4/17/15

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A 405	Continued From page 16 throughout his/her nursing practice while working in Critical Care. The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 11:22 AM, MICU Nurse #2 stated when a physician gives a verbal order for a medication during an intubation or cardiac arrest, s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipation that they physician might order sequential doses. However, per interview on 3/18/15 at 10:15 AM the Medical Director of Adult Critical Care Services acknowledged the drawing up of more medication by nurses then what the physician has ordered during an emergency procedure creates "...a potential for error". Per interview on 3/17/15 at 2:06 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently	A 405	SEE ATTACHED PLAN of Correction	4/17/15

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	470003	A. BUILDING _____ B. WING _____	C 03/19/2015

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A 405	Continued From page 17 had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is "... you draw up what the order is and that is what is expected..." of nurses. Per hospital policy Intravenous Medications; Preparation and Administration of : by RNs and LPNs published on 7/29/14 states " 3. A RN will administer medications via IV push as ordered by a physician and dispensed by the pharmacy."	A 405		
A 490	482.25 PHARMACEUTICAL SERVICES The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This CONDITION is not met as evidenced by: The Condition of Particpaton: Pharmacy Services was not met due to the failure of Pharmacy Services to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital.	A 490	SEE ATTACHED PLAN OF CORRECTION	4/17/15
A 500	Refer to Tag A - 0500 482.25(b) DELIVERY OF DRUGS In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.	A 500	SEE ATTACHED PLAN OF CORRECTION	4/17/15

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A 500	Continued From page 18 This STANDARD is not met as evidenced by: Based on observations, interview and record review the Pharmacy Services failed to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital. (Patient #1) Findings include: During an emergent intubation of a patient in MICU on 1/27/15 the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code	A 500	566 ATTACHED. PLAN of CORRECTION	4/17/15

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A 500	Continued From page 19 procedure efforts were ended and the patient was pronounced dead at 5:16 PM. Per interview on 3/18/15 at 12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the Resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial throughout the hospital. This would provide a safety barrier in preventing a larger dose of Ketamine being drawn and administered during a RCI, noting Nurse #1 had drawn and administered a dose greater than what was prescribed. The Director confirmed, although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the RCI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require. Per observation in MICU on 3/17/15 at 8:40 AM, the RCI medication boxes still contained Ketamine 100 mg/5 cc multidose vials. Per interview on 3/16/15 at 4:10 PM a pharmacist who is the medication safety coordinator confirmed s/he was involved with the RCA and was working on a action plan to replace the multidose vials of 500 mg of Ketamine. "We are pretty close to the result of having a 10 mg/ml vial and 20 cc vial (200 mg)" and further noting the tCUs never use more than 200 mg of Ketamine during an event. The pharmacist also	A 500	SEE ATTACHED PLAN of CORRECTION	4/17/15

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A 600	Continued From page 20 acknowledged a shortage of Ketamine and that further discussions with Anesthesia Services was needed prior to making any changes in Ketamine concentration. The pharmacist further acknowledged proper medication administration is looking at the vial and making sure you have the right dose. Per interview on 3/17/15 at 1:00 PM, the Chief of Anesthesiology acknowledged Anesthesia Services has 2 concentrations of Ketamine, 10 mg/1 cc and 100 mg/1 cc available for the provision of patient care. The Chief of Anesthesiology stated several years ago his/her service requested pharmacy to provide pre-drawn syringes of Ketamine, very low doses of Ketamine 0.1 and 0.2 mg/kg used as an adjunct to reduce opioid dosing. Anesthesia Services does have access to Ketamine 100 mg/1 cc in Pyxis (automated medication station) but there are alerts to assure the right dose is being used. Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services. On 3/19/15 12:10 PM, the Pharmacy Manager for Clinical Practice confirmed Ketamine 500 mg multidose vials had been removed from all the RCI boxes and replaced with 200 mg Ketamine vials.	A 500	SEE ATTACHED PLAN OF CORRECTION	4/17/15